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Manipal Institute of Technology, Manipal

(A Constituent Institute of Manipal University)



II SEMESTER M.TECH (INDUSTRIAL BIOTECHNOLOGY)

END SEMESTER EXAMINATIONS, MAY 2016 / JUNE 2016

SUBJECT: Biopharmaceutical & Pharmaceutical Biotechnology [BIO 524]

REVISED CREDIT SYSTEM

Time: 3 Hours

MAX. MARKS: 50

Instructions to Candidates:

Answer **ANY FIVE FULL** the questions.

✤ Missing data may be suitable assumed.

1A	What are the uses of pharmacokinetic models?										3	
1B	Explain physiological pharmacokinetic model with a neat flow diagram?											3
1C	What are the different theories available to explain the structure of cell membrane and explain it briefly?										4	
2A	Explain the pH – partition hypothesis for the movement of drug molecules across the cell membrane.									3		
2B	Given the follow the trapezoidal r	ving data, rule). Ti Co	collected ime (hr) oncentrati	after a 30 on (mg/L)	0 mg i.v.	bolus dos 2 6 13.8 8.3	e, calcula 12 3.2	te k, Cp ₀ ,	V _d , t _{1/2} , a	nd AUC (us	sing	5
2C	What are the adv	vantages a	and disadv	antages o	f subcuta	neous rou	te of admi	inistration	of drug			2
3A	Derive the math Assume drug for	ematical e llows one	expression compartr	n to detern nent and a	nine appa dministra	rent volur ted via IV	ne of distr 7 Bolus ro	ribution u	sing area	under curve		4
3B	A single IV dos were removed p Calculate elimin	e of an an eriodicall Time (D_u (m nation rate	htibiotic v y and assa hr) 0.25 g) 160 e constant	vas given ayed for pa 0.5 1 140 20 and half-1	to a 50-k arent drug 2 00 250 ife period	g woman g. The foll 4 6 188 46 of drug u	at a dose owing dat	level of 2 ta were of method	20 mg/kg. otained:	Urine sam	ples	4
3C	What is the sign	ificance o	of apparen	t volume o	of distribu	ution?						2
4A	100 mg of a drug were taken perio assayed for drug <u>Time (hr)</u> Plasma Concentration (µg/mL)	g was adm odically af g. The foll 0.25 43	ninistered fter the ad owing day 0.5 32	by rapid 1 ministration ta were ob 1 20	V injection on of drug tained: 1.5 14	on to a 70 g, and the 2 11	-kg, healt plasma fr 4 6.5	hy adult n action of 8 2.8	nale. Bloc each sam 12 1.2	od samples ple was		5
	Calculate rate co	onstants o	t two com	partment	model					1 60		

Reg. No. Image: No. INSPRED BY LFE Ca Constituent Institute of Manipal University) INSPRED BY LFE Ca Constituent Institute of Manipal University) Insufficient of an antibiotic at an infision rate of 15 mg/hr. Blood samples were taken at 8 and at 24 hours and plasma drug concentrations were 5.5 and 6.5 mg/L, respectively. Estimate the elimination half-life of the drug in this patient. 4B A physician wants to administer an anaesthetic agent at a rate of 2 mg/hr by IV infusion. The elimination rate constant is 0.1 hr ⁻¹ , and the volume of distribution (one compartment) is 10 L. What loading dose should be recommended if the doctor wants the drug level to reach 2µ g/mL immediately? f 5A Two drugs, A and B, have the following pharmacokinetic parameters after a single oral dose of 500 mg: f 5B Is clearance a better parameter to describe drug elimination than half-life? Why is it necessary to use both parameters in the literature? f 5C Develop the mathematical expression to predict the plasma drug concentration when the drug is given to the parameters in the literature? f 5C Discuss the different steps involved in hard capsule manufacturing process? f 6C Explain different steps involved in wer granulation process. & dry granulation process. f								<u> </u>	
Manipal Institute of Technology, Manipal (A constituent Institute of Manipal University)Instruction of an antibiotic at an infusion rate of 15 mg/hr. Blood samples were taken at 8 and at 24 hours and plasma drug concentrations were 5.5 and 6.5 mg/L, respectively. Estimate the elimination half-life of the drug in this patient.48A physician wants to administer an anaesthetic agent at a rate of 2 mg/hr by IV infusion. The elimination rate constant is 0.1 hr ⁻¹ , and the volume of distribution (one compartment) is 10 L. What loading dose should be recommended if the doctor wants the drug level to reach 2µ g/mL immediately?54Two drugs, A and B, have the following pharmacokinetic parameters after a single oral dose of 500 mg:55Drug k_{a} (hr ⁻¹) k (hr ⁻¹) V b (mL) A 1.0 0.2 10,00056Both drugs follow a one-compartment pharmacokinetic model and are 100% bioavailable. Calculate the r max and C max for each drug56Is clearance a better parameter to describe drug elimination than half-life? Why is it necessary to use both parameters in the literature?56Discuss the different steps involved in hard capsule manufacturing process?66Explain the working principle of roller compaction?			Reg. No.						
 An antibiotic has an elimination half-life of 4 hours in the general population. A patient was given an IV infusion of an antibiotic at an infusion rate of 15 mg/hr. Blood samples were taken at 8 and at 24 hours and plasma drug concentrations were 5.5 and 6.5 mg/L, respectively. Estimate the elimination half-life of the drug in this patient. A physician wants to administer an anaesthetic agent at a rate of 2 mg/hr by IV infusion. The elimination rate constant is 0.1 hr⁻¹, and the volume of distribution (one compartment) is 10 L. What loading dose should be recommended if the doctor wants the drug level to reach 2µ g/mL immediately? Two drugs, A and B, have the following pharmacokinetic parameters after a single oral dose of 500 mg: Drug k a (hr⁻¹) k (hr⁻¹) V D (mL) A 1.0 0.2 10,000 Both drugs follow a one-compartment pharmacokinetic model and are 100% bioavailable. Calculate the t max for each drug Is clearance a better parameter to describe drug elimination than half-life? Why is it necessary to use both parameters in the literature? Develop the mathematical expression to predict the plasma drug concentration when the drug is given to the patient by IV infusion (Assume drug is eliminating by first order and follows one compartment model) Explain different steps involved in hard capsule manufacturing process? Explain the working principle of roller compaction? 		प्रज्ञानं ब्रह्म Manipal Institution Manipal (A Constituent INSPIRED BY LIFE (A Constituent)	ute of Tecl at Institute of Ma	nnolo nipal Ur	D gy, N niversity)	/Iani	pal ⁽	KNOWLEDGE IS POWER	
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